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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin E. Schwab

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EXAMINER

KOLKER, DANIEL E

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/830,972	Applicant(s) SCHWAB ET AL.	
	Examiner DANIEL KOLKER	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 127-132 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 127-132 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment (2 pages)</u> |

DETAILED ACTION

1. The amendment after final rejection, filed on 17 March 2008, has been entered. Claims 127 – 132 are pending.
2. The rejections made of record in the office action mailed 9 January 2008 are moot; all claims that had been rejected have been canceled in the amendment filed 17 March 2008.
3. The indicated allowability of claims 127 – 132 is withdrawn in view of the newly discovered reference(s) to Cao. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 127 – 132 are rejected under 35 U.S.C. 102(e) as being anticipated by Cao (U.S. Patent Application Publication 2005/0084850, published 21 April 2005, filed 16 January 2003, claiming benefit of earlier-filed applications 17 January 2001 and 16 December 1998, as well as provisional application 60/101603, filed 24 September 1998. The relevant nucleic acid is disclosed in the '603 application).

Cao teaches SEQ ID NO:5, which comprises a sequence that encodes a protein 99.1% identical to residues 1-172 of SEQ ID NO:29 fused to the carboxy-terminal 188 residues of SEQ ID NO:29. See enclosed sequence alignment; see also Cao paragraph [0031] and claim 11. While the sequence from Cao has additional nucleotides after those nucleotides encoding residue 172 of applicant's SEQ ID NO:29, the prior art sequence is 99.1% identical to a sequence encoding the fusion protein above. Given the very high degree of homology between the two sequences, they will hybridize under the conditions recited in claim 127. Additionally, since the prior art nucleic acid sequence comprises nucleic acids that encode every amino acid in the fusion protein, the protein will necessarily have the function recited in claim 127, i.e. it will

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display inhibitory activity in an NIH 3T3 fibroblast spreading assay. See MPEP §§ 2112(III) and 2112.01 for a discussion of rejections based on inherency when the prior art teaches an identical or substantially identical product, but is silent with respect to a property recited in the claim. Thus Cao's SEQ ID NO:5 anticipates claim 127.

Claim 128 is anticipated as the limitation "amino acids 1-172 fused to the carboxy-terminal 188 amino acids of SEQ ID NO:29" is anticipated by Cao's SEQ ID NO:5. This element of the claim does not explicitly require that there be no intervening nucleic acids between those encoding residue 172 and residue 990 of SEQ ID NO:29 (residue 990 being the 188th from the C-terminus). The claim language allows for at least some degree of intervening sequence, so long as the relevant nucleic acids are fused. Note that at the time the invention was made, it was understood that fusion proteins can have short sequences linking the relevant functional domains of the molecule, and that nucleic acid sequences encoding such linkers are commonly inserted between the nucleic acids encoding the functional domains. See for example Fischer (1997. *Nature Biotechnology* 15:142-145), particularly Figure 1B and p. 145 first complete paragraph. Note that while the enclosed sequence alignment does not show a direct alignment for the serine residue at position 990 (the serine residue following residue 172 of SEQ ID NO:29), the stretch of nucleotides that comprise the insertion in Cao's sequence include the serine-encoding triplet AGC at nucleotides 661-663 and the serine encoding triplet AGT at nucleotides 683-685. For applicant's convenience, the examiner has underlined these triplets on the enclosed sequence alignment. Thus the prior art sequence (Cao's SEQ ID NO:5) encodes "amino acids 1-172 fused to the carboxy-terminal 188 amino acids of SEQ ID NO:29". Note that Cao teaches that the nucleic acids described in the invention can be placed in vectors; see paragraph [0035]. Therefore Cao's publication anticipates claim 128 as well.

Claims 129 - 131 are anticipated as Cao teaches cells comprising the disclosed vectors, including both prokaryotic and eukaryotic cells (see paragraphs [0036] – [0037]. Claim 132 is anticipated as Cao teaches methods of producing recombinant protein by culturing the relevant cells transformed with nucleic acid; see for example paragraph [0130].

Note that Cao claims the same patentable invention as applicant; since this reference is a U.S. Patent Application Publication claiming the same patentable invention, a declaration under 37 CFR 1.131 may be not be appropriate if applicant is to attempt to overcome the reference by antedating it. See 37 CFR 1.131(a)(1) and MPEP § 715(II)(B).

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Conclusion

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

April 23, 2008